REMARKS

Claims 6-11 are pending. Claim 6 is amended herein.

Support for amendments

Claim 6 is amended to make clear that the nature of the antibody produced is an "anti-idiotypic, antiembryonic antiserum". This phrase is supported by description in the specification at page 3, lines 16-17. Step v) of claim 6 is amended to recite that kidney, lung and liver organs should be used in the step and that these organs should be obtained from a normal rat. Such is disclosed at page 2, lines 6-8, which describe normal kidney as including a "heteroantigen", defined as an antigen that is expressed in both normal tissues and in tumors, expressed in hepatoma, and lung and liver as including a heteroantigen expressed in renal adenocarcinoma.

Telephone interview

Claims 6-11 stand rejected under 35 USC §112, first paragraph, for alleged lack of enablement. Applicants have previously addressed this issue, presenting a detailed analysis of the factors to be considered in weighing the question of enablement, in their paper filed February 10, 2006. The Examiner was not completely persuaded and so a telephone interview was held with the Examiner on May 25, 2006. This paper reflects the substance of that discussion.

The Examiner expressed concerns about the lack of clear disclosure about what is actually done to prepare the antiserum. She indicated that, were the antiserum one directed against a usual antigen, there would not be much problem. However, she said that, in view of the fact that the present antiserum is an anti-idiotypic antiserum, the problems presented by trying to adsorb out antibodies against antigens on normal tissues were expected to be somewhat greater than normal, and so more detail of this step (*i.e.* step v)) should be described.

Applicant's Representative replied that the anti-idiotypic nature of the antiserum does not suggest that the step of removing antibodies that bind to antigens presented by normal tissues is

more complicated for this invention than for any other antiserim. This is because the antiserum is used for a diagnostic reagent, and regardless of whether anti-idiotypic antibodies that represent the shape of antigens of normal organ antigens are in the antiserum, their presence does not influence the result. The problems of false diagnosis arise when anti-idiotypic antibodies are present in the antiserum that specifically bind to antigens presented by normal cells, as then they agglutinate the normal cells present in the sample. So long as these can be removed, step v) of claim 6 is correctly accomplished.

The present specification and claim 6 indicate that antigens that bind to antigens present on normal cells must be removed, and the specification indicates that this is done by adsorbing the antiserum with organs that normally express so-called "heteroantigens", further stating the examples of kidney, lung and liver.

The Examiner seemed to be persuaded by this argument.

The Examiner then raised an additional issue that, in tumor tissue, there are usually tumor-infiltrating lymphocytes, and so use of tissues from animals with tumors for the adsorption step would be a problem. Therefore the term "normal" is used to describe the organs used in the adsorption step. The Examiner agreed this amendment would be helpful if supported by the specification.

Finally the question of how one of skill in the art determines that an obtained antiserum is operative was discussed. Applicant's Representative pointed out that the threshold diagnostic test described in the specification could be used with samples from known normal and known cancer patients. The Examiner seemed to accept this explanation as satisfactory.

Claim 6 is amended in a manner consistent with the arguments the Examiner accepted as persuasive. Accordingly the present claims 6-11 are believed to be in condition for allowance.

Should there be any further minor matters to be resolved that can be addressed by a telephone discussion, the Examiner is invited to contact the undersigned at 703-205-8043.

Dated: June 12, 2006

Respectfully submitted,

By _____

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